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5.0 510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation: 06. February 2007
Company / Institution name: **RICHARD WOLF MEDICAL INSTRUMENTS CORP.**			FDA establishment registration number: 14 184 79
Division name (if applicable): N.A.			Phone number (include area code): (847) 913 1113
Street address: 353 Corporate Woods Parkway			FAX number (include area code): (847) 913 0924
City: Vernon Hills	State/Province: Illinois	Country: USA	ZIP / Postal Code: IL 60061
Contact name: Mr. Robert L. Casarsa			
Contact title: Quality Assurance Manager			

Product Information:

Trade name: "S-line" S(a)line Bipolar Resectoscope, Electrode and Cable	Model number: 8680.xxx / 46XX.xxx / 8108.2xx
Common name: Bipolar resectoscope	Classification name: Resectoscope

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K980302	1 Resectoscopes E-line	1 Richard Wolf
2 K042523	2 Resection Pump and Resectoscope for Chip Aspiration (Resection Master)	2 Richard Wolf
3. Not known	3. Bipolar resectoscope	3. Olympus
4 K031001	4 ACMI Vista CTR Bipolar Loop Electrode	4 ACMI
5 K022480	5 ACMI Disposable Bipolar Cord	5 ACMI
6 Not known	6 Plasma Kinetic Tissue Management System	6 Gyrus

1.0 Description

The bipolar S-line Resectoscopes with electrodes have a design similar to the traditional monopolar resectoscopes, but with an additional pin for the neutral pole at the working element. The HF bipolar connection cables have a standard resectoscope connector and in addition a neutral connector for connection to the neutral pin at the S-line working element and on unit side plugs for connection to bipolar generators.

2.0 Intended Use

S(a)line Resectoscopes are used for endoscopically controlled removal (ablation) of tissue using 0.9% NaCl solution (saline) as the irrigation medium.

For Urology:

Urological surgical procedures involving the ablation or removal of soft tissue and where associated hemostasis is required.

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Transurethral resection of the prostate (TURP) and bladder neck. Pg 7 of 7
Transurethral resection of the bladder tumors (TURBT).
Transurethral incision of the prostate.
Coagulation of bleeding in the lower urinary tract.

For Gynecology:
Tissue cutting, removal, and desiccation as required or encountered in gynecologic hystroscopic electrosurgical procedures for the treatment of intrauterine myomas, polyps, adhesions, septa, and benign conditions requiring endometrial ablation.

Excision of intrauterine myomas.
Excision of intrauterine polyps.
Lysis of intrauterine septa.
Endometrial ablation.

3.0 Technological Characteristics

Besides the standard HF connection at the working element, which is connected to the active area of the electrode, there is an additional pin for the neutral HF-connection. The neutral pin is connected to the working element that has a conductive connection to the resectoscope sheath, optic and finally to the forks of the electrode.
The saline used in bipolar resectoscope applications can minimize adverse effects. The Purisole or Glycine that is used in monopolar resectoscope applications can cause adverse effects, such as TUR-Syndrome, if the solution enters the blood stream. In addition, intra-operative muscle tremor (stimulation of nerve obturatorius) is largely avoided, because the applied HF current is directed from the active area through the conductive fluid to the forks of the electrode, optic, sheath and working element, without running through the body of the patient to the neutral electrode as in monopolar applications.

4.0 Substantial Equivalence

The submitted devices pose the same type of questions about safety or effectiveness as the compared devices and the new technological characteristics have not diminished safety or effectiveness. The submitted devices are substantially equivalent to existing 510(k)-cleared devices sold by Richard Wolf, Gyrus, and ACMI.

5.0 Performance Data

No performance standards are known.

6.0 Clinical Tests

No clinical tests performed.

7.0 Conclusions Drawn

These devices are designed and tested to guarantee the safety and effectiveness, when used according to the instructions manual.

By: Robert L. Casarsa
Robert L. Casarsa
Quality Assurance Manager

Date: Feb 12, 2007

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAR 2 2 2007

Mr. Robert L. Casarsa
Quality Assurance Manager
Richard Wolf Medical Instruments Corporation
353 Corporate Woods Parkway
VERNON HILLS IL 60061-3110

Re: K062720
Trade/Device Name: S-Line Bipolar resectoscopes and bipolar electrodes
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Codes: FJL, FDC, FAS and HIH
Dated: February 28, 2007
Received: March 2, 2007

Dear Mr. Casarsa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4.0 Indications for Use

510(k) Number (if known): K062720

Device Name: S-Line Bipolar resectoscopes and bipolar electrodes

Intended use: S(a)line Resectoscopes are used for endoscopically controlled removal (ablation) of tissue using 0.9% NaCl solution (saline) as the irrigation medium.

For Urology:
Urological surgical procedures involving the ablation or removal of soft tissue and where associated hemostasis is required.

Transurethral resection of the prostate (TURP) and bladder neck.
Transurethral resection of the bladder tumors (TURBT).
Transurethral incision of the prostate.
Coagulation of bleeding in the lower urinary tract.

For Gynecology:
Tissue cutting, removal, and desiccation as required or encountered in gynecologic hystroscopic electrosurgical procedures for the treatment of intrauterine myomas, polyps, adhesions, septa, and benign conditions requiring endometrial ablation.

Excision of intrauterine myomas.
Excision of intrauterine polyps.
Lysis of intrauterine septa.
Endometrial ablation.

Prescription Use ✓ AND/OR Over-The Counter Use

(Part 21CFR 801 Subpart D) (Part 21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062720

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